REMARKS

The pending claims are claims 1-21, and 31-48.

Submission of Supplemental Information Disclosure

In compliance with the ongoing duty of disclosure imposed by 37 C.F.R. §1.56, Applicants submit herewith a Supplemental Information Disclosure Statement and PTO Form 1449.

Power of Attorney

Applicants include herewith an executed Power of Attorney form that revokes the previously filed Power of Attorney and appoints new representation with new Attorney Docket Number **025129.00006**. Further, Applicant has requested a Change of Correspondence, so that all communications from the USPTO be sent to the following contact and address:

Tristan Fuierer
Moore & Van Allen, PLLC
P.O. Box 13706
Research Triangle Park, NC 27709

In addition, pursuant to the new Power of Attorney submitted herein, the Customer Number should be changed to **24239**.

Entity Status of New Assignee

The new assignee of the subject patent application, Tiber Laboratories, qualifies as a small entity.

Amendment to the Claims

Claims 1 and 31 have been amended. Support for the amended claims can be found throughout the specification and claims as originally filed at, for example, at page 4, line 3 through page 5, line 20 and original claims 1 and 31.

No new matter has been added herein.

Claim Rejections – 35 U.S.C. §112, Written Description Requirement

In the October 6, 2006 Office Action, claims 1-21, 31-48 and 53 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for containing subject matter that was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that:

> "The claims in this application introduce new limitation into the claimed invention, namely "dosage units." The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification" (see, *e.g.*, Office Action dated October 6, 2006 at page 3, lines 4-7).

The Examiner further stated that:

> "With respect to the 'homogeneous suspension being in an amount including a plurality of dosage units present' ... The specification discloses that the pharmaceutical composition of the present invention is prepared in a single dosage form, wherein said single dosage forms include suspension and tablets (page 4, lines 4-9). Reading the entire specification, those skilled in the art would have understood that tannate salts of pyrilamine and phenylephrine is prepared in a single dosage form, not plurality of dosage form [sic]. The instantly claimed plurality of dosage forms includes a possibility that each of phenylephrine and pyrilamine is present in different dosage forms, for example phenylephrine in tablet and pyrilamine in suspension respectively. Clearly, there is no support in the specification that said tannate salts of pyrilamine and phenylephrine is being present in multiple dosage forms in said composition." (see, *e.g.*, Office Action dated October 6, 2006 at page 3, line 19 through page 4, line 12).

Claims 1 and 31 have been amended to remove the offending terms "plurality of dosage units" and "homogeneous suspension," thus rendering the rejection moot as it pertains to these claims. Claim 53 has been cancelled herein. Applicants respectfully request that the Examiner withdraw this rejection under 35 U.S.C. §112, first paragraph.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

In the October 30, 2006 Office Action, claims 1, 31 and 53 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner stated:

> "Independent claims 1, 31 and 53 recite 'homogeneous suspension being in an amount including a plurality of dosage units, the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.'
>
> It is not clear what is meant by "being in amount including a plurality of dosage units…when compared with each of the other dosage units," and the specification does not define how to ascertain the requisite degree of concentration or amounts of the active ingredients in 'dosage units.'" Furthermore, it is not clear what is being compared with." (see, *e.g.*, Office Action dated 10/30/2006 at page 6, lines 4- 12).

Claims 1 and 31 have been amended to remove the offending terms "homogeneous suspension being in an amount including a plurality of dosage units" and "the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units," thus rendering the rejection moot as it pertains to these claims. Applicants respectfully request that the Examiner withdraw this rejection under 35 U.S.C. §112, second paragraph.

Claim Rejections Under 35 U.S.C. §103(a)

In the October 6, 2006 Office Action, claims 1-21, 31-48 and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gordziel (U.S. Patent No. 6,287,597, hereinafter "Gordziel") in view of Chopdekar *et al.* (U.S. Patent No. 5,599,846, hereinafter "Chopdekar"). Specifically, the Examiner stated that:

> "Gordziel discloses a composition consisting essentially of phenylephrine tannate and pyrilamine tannate and the unspecified components such as benzoic acid, coloring, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methyl paraben, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol, wherein said

> composition is prepared in a conventional manner; … Chopdekar discloses an antihistamine tannates (e.g., phenylephrine, pyrilamine, etc…) prepared by water route. Chopdekar teaches or suggests the advantage of preparing antihistamine tannates in water route compared to the conventional isopropanol route, wherein the water route yields about 90-97% of the tannate salts products and about 90-98% of the product purity compared to only about 70% of the yields and about 85-90% of the purity in the isopropanol route." (see, *e.g.*, Office Action dated October 6, 2006, at page 7, line 11 through page 8, line 2).

The Examiner concluded by stating that:

> "One having ordinary skill in the art would have been motivated to prepare the claimed composition by the water route such that the yield and the purity of antihistamine (pyrilamine and phenylephrine) tannates would be greatly increased. Although the prior art references in combination do not specifically disclose the claimed order (or step) of preparing said composition, such determination of order of performing step is prima facia obvious in the absence of new or unexpected results." (see, *e.g.*, Office Action dated October 6, 2006, at page 10, line 18 through page 9, line 2).

Applicants respectfully traverse this rejection.

In order to establish a *prima facia* case showing obviousness over the prior art, the Examiner must show the following three elements: (1) a suggestion or motivation to combine or modify the cited references; (2) a reasonable expectation of success; and (3) that the combination or modification of the prior art references teaches all of the limitations of the claim at issue. Failure to show any one of the foregoing negates a *prima facia* showing. The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. M.P.E.P. §2142 *et seq*.

Merely identifying all of the elements of a claim or their equivalents in the prior art is not sufficient. Almost all inventions are combinations of old elements, and an Examiner may often find every element of a claimed invention in the prior art. If this finding were sufficient "to negate patentability, very few patents would ever issue." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Therefore, in order to establish a *prima facia* rejection for obviousness, an "examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would [***not*** could] select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357

(Fed. Cir. 1998).

Applicants submit that the composition claimed in the present invention exhibits a greater level of reduced variability in active drug content and a significantly increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range. These enhanced properties, as claimed in the present application, are a result of the novel process of converting the tannate salts of the active pharmaceutical ingredients *in situ*. Specifically, the present invention requires three novel steps in order to achieve these enhanced properties. First, the conversion process of the present invention begins with the free base or common salt form of the active ingredient, thereby reducing the level of variability of the tannate salts after the *in situ* conversion. Second, the present invention utilizes a separate dispersion that prevents the aggregation of the tannate salts as they precipitate out of solution. Third, the combining of the tannate salts with the at least one suspending agent is done *without isolation and purification*. The end result of these three novel steps is a composition that has significantly reduced levels of variability of the active pharmaceutical ingredients (*i.e.*, the tannate salts) and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range.

Turning to the references cited by the Examiner, Applicants assert that neither of these references, alone or in combination, disclose or suggest a composition that will exhibit the same level of reduced variability in active drug content and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range as claimed in the present application. As acknowledged by the Examiner, Gordziel only teaches the previously known method of using isopropanol to prepare compositions including pyrilamine and phenylephrine. As a result, Applicants submit that it cannot be the case that the composition disclosed in Gordziel is the same as the composition claimed in the present application. Applicants further submit that the addition of the Chopdekar does not remedy the deficiency of the Gordziel reference. Chopdekar discloses a method of purifying tannate salts using water, however, the process requires a freeze-drying step to remove excess water. This freeze-drying step is contra to Applicants *in situ* conversion process, since Applicants process does not require any "isolation or purification" of the tannate salts. As a result, the method described by Chopdekar does not, and will not, result in a composition that has same level of reduced variability in active drug content and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range and claimed in the present invention.

In view of the above, Applicants assert that the combination of the Gordziel and Chopdekar references do not teach all of the limitations of independent claims 1 and 31 as presently pending, and further assert that the process of the independent claims renders a product different from that produced by Gordziel alone or in combination with Chopdekar. As such, Applicants respectfully request a withdrawal of the rejection of claims 1-21, 31-48 and 53 under 35 U.S.C. §103(a).

Obviousness-Type Double Patenting

The Examiner has provisionally rejected claims 1-21, 31-48 and 53 under the judicially created doctrine of obviousness-type double patenting over claims 1-21, 31-48 and 53 of U.S. Patent Application No. 10/645,977.

When the obviousness-type double patenting rejection is the only rejection remaining to the presently pending case AND **if** the presently pending claims are an obvious variation of the invention defined in claims 1-21, 31-48 and 53 of co-pending U.S. Patent Application No. 10/645,977 (which can only be objectively assessed when the only rejection remaining in the presently pending case is the obviousness-type double patenting rejection), Applicants will consider submitting the required terminal disclaimer.

Petition for Extension of Time/Fees Payable

Applicants hereby petition for a three (3) month extension of time, extending the deadline for responding to the October 6, 2006 Office Action from January 6, 2007 to April 6, 2007. The fee of $510.00 specified in 37 C.F.R. §1.17(a)(1) for such three (3) month extension is hereby enclosed.

In addition, the fee under 37 CFR §1.17(p) of $180.00 for the filing of the Supplemental IDS is also enclosed.

The total fee of $690.00 is being paid by Electronic Funds Transfer. Authorization is hereby given to charge any deficiency in applicable fees for this response to Deposit Account No. 13-4365 in the name of Moore & Van Allen, PLLC.

Conclusion

Claims 1-21 and 31-48 are in form and condition for allowance. If any additional issues remain,

the Examiner is requested to contact the undersigned attorney at (919) 286-8021 to discuss same.

Respectfully submitted,

MOORE & VAN ALLEN PLLC

Date: 4-6-07

By: _____

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